

**IN THE UNITED STATES DISTRICT COURT  
FOR THE NORTHERN DISTRICT OF OKLAHOMA**

**IN RE: GENENTECH HERCEPTIN )  
(TRASTUZUMAB) MARKETING )  
AND SALES PRACTICES )  
LITIGATION )                   **MDL DOCKET NO. 16-MD-2700**  
                                 **ALL CASES****

**FILED UNDER SEAL**

**OPINION AND ORDER**

Before the Court are Plaintiffs' Motion to Compel (Doc. 64) and Defendant's Motion for Protective Order (Doc. 124). These pending motions are construed to seek production of all unanswered preemption discovery requested by Plaintiffs to date, as set forth in the Parties' Joint Submission Regarding Preemption Discovery ("JDS") (Doc. 130).

**I. Procedural History**

As set forth in the Court's Order Opinion and Order dated March 28, 2017 ("3/28 Order") (Doc. 187), the Court decided to maintain Phase I despite delays caused by the pending discovery disputes.<sup>1</sup> Phase I is governed by Case Management Order #1 (Doc. 39 (explaining Phase I)) and Case Management Order #2 (Doc. 188 (amending Phase I deadlines)). Phase I is limited to discovery and briefing on Defendant's Amended Motion for Summary Judgment on the Issue of Preemption (Doc. 200). In the 3/28 Order, the Court stated:

After consideration of all parties' positions and consultation with Judge Wilson, the Court concludes that maintaining Phase I continues to have value. Having now reviewed the preemption motion, the Court remains convinced that the preemption issue should be decided prior to class or merits discovery and prior to consideration of other motions. However, the Court now has a more realistic view of the discovery required for resolution of the preemption motion, and it is more extensive than Defendant forecasted at the initial hearing. Defendant's preemption motion relies upon evidence regarding its communications with FDA and its manufacturing process, both of which Plaintiffs are entitled to explore before responding to the

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<sup>1</sup> This Opinion and Order assumes familiarity with the 3/28 Order, which is incorporated by reference.

motion. As observed by Judge Wilson . . . , the preemption defense opened doors in discovery that may well have stayed closed if the only issue was breach of a state-law warranty. Thus, while the Court still believes Phase I is in the interest of judicial economy, the Court no longer views Phase I as a short and expedited process with limited discovery. Instead, the Court anticipates that “preemption discovery” may take significant additional time and effort. The Court will set a Phase I discovery deadline six months from this date. The Court is hopeful that future phases of the litigation (if they occur) are expedited by the discovery efforts undertaken during Phase I.

(Doc. 187 at 5-6.) After offering these broad observations regarding discovery, the Court noted that Judge Wilson would decide the specific pending discovery motions.

Effective April 17, 2017, Judge Wilson resigned from his position, and there is currently no magistrate judge assigned to this action. Therefore, the Court hereby withdraws reference of the pending discovery motions and resolves the pending discovery disputes by this written Order. The Court has reviewed the briefing on the two pending motions, the JDS, and transcripts of the hearings conducted by Judge Wilson.

## **II. Legal Standard**

Federal Rule of Civil Procedure 26(b)(1) provides:

Parties may obtain discovery regarding any nonprivileged matter that is relevant to any party’s claim or defense and proportional to the needs of the case, considering the importance of the issues at stake in the action, the amount in controversy, the parties’ relative access to relevant information, the parties’ resources, the importance of the discovery in resolving the issues, and whether the burden or expense of the proposed discovery outweighs its likely benefit. Information within this scope of discovery need not be admissible in evidence to be discoverable.

The Advisory Committee Note to the 2015 Amendment explains that the proportionality language now contained in Rule 26(b)(1) “restores the proportionality factors to their original place in defining the scope of discovery,” but is not intended to “place on the party seeking discovery the burden of addressing all proportionality considerations.” Fed. R. Civ. P. 26, Adv. Comm. Notes, 2015

Amendment.

In addition to proportionality considerations explained above, a court “must limit the frequency or extent of discovery” if the Court determines: (1) the discovery sought is unreasonably cumulative or duplicative, or can be obtained from a less burdensome source; (2) the party seeking discovery has had ample opportunity to obtain the information; or (3) the discovery is outside the scope of Rule 26(b)(1). Fed. R. Civ. P. 26(b)(2)(C)(i)-(iii). Further, with respect to electronically stored information (“ESI”), a party need not provide discovery if a party shows that the ESI is “from sources that are not reasonably accessible because of undue burden or cost,” unless the requesting party then shows good cause. Fed. R. Civ. P. 26(b)(2)(B).

### **III. Plaintiffs’ Motion to Compel (Doc. 64)**

The Court has organized its rulings on Plaintiffs’ Motion to Compel by categories, in accordance with the JDS.

#### **A. Genentech’s Correspondence with Food and Drug Administration (“FDA”) Regarding Herceptin Labeling (I on JDS)**

##### **1. Rulings**

Request No. 6 (June 2016) - Produce all correspondence between Genentech and the FDA relating to Herceptin’s Labeling, including but not limited to correspondence relating to the “Chemistry, Manufacturing and Controls” section of the Herceptin Biologics License Application (“BLA”) submitted to the FDA by Genentech. - **GRANTED. Requested discovery shall be produced from Defendant’s described regulatory database and custodial files.**

Request No. 15 (June 2016) - Produce all Establishment Inspection Reports, FDA Form 483s, and Warning Letters issued by the FDA relating to the labeling of Herceptin, the amount of Herceptin

contained in a multi-dose vial (either in the form of Herceptin Cake or reconstituted Herceptin solution), or the concentration of Trastuzumab in the reconstituted Herceptin solution. - **GRANTED.**

**Requested discovery shall be produced from Defendant's described regulatory database.**

## **2. Analysis - Communications After FDA Approval**

Plaintiffs argue that this discovery is relevant to overcoming Defendant's impossibility preemption defense. According to Plaintiffs, this evidence is relevant to whether Defendant can show "clear evidence that the FDA would not have approved a change to [Herceptin's] label." *See Wyeth v. Levine*, 555 U.S. 555, 571 (2009). Defendant contends that the proper inquiry is whether Defendant could "independently do under federal law what state law requires of it," *PLIVA, Inc. v. Mensing*, 564 U.S. 604, 620 (2011), and that it could not, as a matter of law, make a unilateral label change that would satisfy the state-law obligation alleged in Plaintiffs' Complaint. Therefore, Defendant argues, no further discovery should be permitted.

A trilogy of Supreme Court decisions on impossibility preemption – *Wyeth v. Levine*, 555 U.S. 555 (2009); *PLIVA, Incorporated v. Mensing*, 564 U.S. 604 (2011); *Mutual Pharmaceutical Company, Incorporated v. Bartlett*, 133 S. Ct. 2466 (2013) – invite dispute over the standard applicable to Defendant's impossibility preemption argument. *See Bartlett*, 133 S. Ct. at 2480 (explaining that Court "would welcome Congress' explicit resolution of the difficult pre-emption questions that arise in the prescription drug context" and that the issue "has repeatedly vexed the Court – and produced widely divergent views – in recent years") (citing *Wyeth* and *Mensing*). Further, none of the three cases is a precise factual fit because: (1) the defendants in *Mensing* and *Bartlett* were generic drug manufacturers, unlike Defendant; and (2) the underlying state-law claims involved failures to warn or design defects that caused personal injuries, unlike Plaintiffs' claims.

For purposes of discovery, the Court need not (and does not) reach a conclusion as to how these decisions will ultimately apply to the evidence. The Court is satisfied that *Wyeth* is not wholly inapplicable, expressly overruled by subsequent cases, or otherwise irrelevant to Defendant's impossibility preemption argument. Defendant argues that it is not raising a *Wyeth*-type preemption defense and that Plaintiffs "have no need for discovery relating to an argument [it] will never make." (JDS 10 n.5.) This Court – and not Defendant – will ultimately decide how to apply Supreme Court law to the evidence presented. Plaintiffs are entitled to advocate for the *Wyeth* standard, and their requested discovery is relevant to the impossibility preemption analysis in *Wyeth*. See 555 U.S. at 1196-97 (discussing record evidence as to defendant's awareness of prior incidents, its communications with FDA, and that it "worked with the agency to change Phenergan's label" over thirty years prior to the injury suffered in 2000).

Even assuming Plaintiffs' sole method of defeating impossibility preemption is showing that Defendant could have unilaterally changed its label under 21 C.F.R. § 601.12(f)(2)(i)(c) – as argued by Defendant – the requested discovery is also relevant to that inquiry. Specifically, the discovery is relevant to whether Defendant could have submitted a unilateral labeling change to "reflect newly acquired information . . . to accomplish . . . add[ing] or strengthen[ing] an instruction about dosage and administration that is intended to increase the safety of the use of the product." 21 C.F.R. § 601.12(f)(2)(i)(c). Defendant contends that Plaintiffs cannot possibly uncover any "newly acquired information" because FDA knew about and approved a particular protein content range when the drug was approved, which ends the inquiry. (See JDS 12 n.7.) In so arguing, Defendant essentially urges the Court to credit its expert's testimony rather than allow Plaintiffs the opportunity to develop their own evidence and method of responding to the preemption arguments. The Court rejects this

approach and finds the requested discovery relevant to impossibility preemption under both parties' proposed standards.

With respect to proportionality, granting these discovery requests will require search of an extensive regulatory database containing over four million documents, according to Defendant. The Court finds this proportional to the needs of the case, considering the importance of the issues raised in this multi-district litigation action, the substantial amount in controversy, Defendant's access to relevant information, Defendant's resources, and the importance of the discovery in resolving the issues. Defendant elected to raise both obstacle and impossibility preemption to defeat Plaintiffs' claims. Plaintiffs will be deprived of resolution of their state-law claims if the defense is successful. The burden on Defendants does not outweigh the likely benefit of the Court being assured that, when and if it dismisses Plaintiffs' claims with prejudice based on federal preemption, it does so based on a fair and complete evidentiary record rather than on Defendant's version of scientific and other evidence. It is not unusual to impose significant discovery burdens on a defendant or to have a lengthy discovery period on federal preemption in the prescription-drug context. *See Dobbs v. Wyeth Pharm.*, 797 F. Supp. 2d 1264, 1280 (W.D. Okla. 2011) (discussing extensive evidentiary record on issue of federal preemption); *Pinsonneault v. St. Jude Med., Inc.*, No. 12-CV-1717 PJS/JSM, 2014 WL 2879754, at \*3 (D. Minn. June 24, 2014) (noting that plaintiffs "had an entire year to conduct discovery on the issue of preemption").

### **3. Analysis - Communications Before FDA Approval**

Request No. 6 extends to communications occurring before FDA approval, which requires additional analysis. The Court finds that communications occurring prior to FDA approval relating to the "Chemistry, Manufacturing and Controls" section of the BLA are relevant to obstacle

preemption. Defendant argues that compliance with the alleged state-law standard would pose an “obstacle” to the federal regulatory scheme permitting reasonable variations in food and drug packages, as set forth in part in 21 C.F.R. § 201.51(g), and the specific variation permitted by FDA regarding Herceptin. Plaintiffs are entitled to discovery on the approval process for the purpose of exploring whether FDA “weighed the competing interests relevant to the particular requirement in question, reached an unambiguous conclusion about how those competing interests should be resolved . . . , and implemented a conclusion via a specific mandate . . . .” *Farina v. Nokia Inc.*, 625 F.3d 97, 125 (3d Cir. 2010) (cited by Defendant as relevant inquiry regarding obstacle preemption). This is distinguishable from using the evidence to prove Defendant committed fraud on FDA or that FDA did a sub-standard job of reviewing Defendant’s BLA.

Although discoverable for purposes of obstacle preemption, the Court clarifies that communications occurring prior to FDA approval are not relevant to impossibility preemption. *See In re Celexa & Lexapro Mktg. & Sales Practices Litig.*, 779 F.3d 34, 41 (1st Cir. 2015) (“Wyeth effectively reserves the launch of new drugs to the expertise of the FDA, but then preserves a wide scope for the states in requiring manufacturers to respond to information not considered by the FDA.”). Nor are they relevant to assist Plaintiffs in showing that Defendant committed fraud or made misleading statements to the FDA regarding Herceptin during the approval process. *In re Incretin Mimetics Prod. Liab. Litig.*, No. 13MD2452 AJB MDD, 2014 WL 4987877, at \*4 (S.D. Cal. Oct. 6, 2014) (holding that policy underlying the Supreme Court’s holding in *Buckman Company v. Plaintiffs’ Legal Committee*, 531 U.S. 341 (2001), precludes Plaintiffs from “asserting fraud-on-the-FDA type claims as a defense to federal preemption or as other-wise relevant to a preemption analysis”).

**B. Documents Regarding the FDA Approval Process (II on JDS)**

**1. Rulings**

Request No. 4 (Oct. 2015) - Produce all documents and communications related to the FDA approval process for Herceptin. - **GRANTED. Requested discovery shall be produced from Defendant's described regulatory database and custodial files.**

Request No. 7 (June 2016) - Produce all "Changes Being Effected" submitted to the FDA by Genentech relating to Herceptin - **GRANTED. Requested discovery shall be produced from Defendant's described regulatory database.**

Request No. 9 (June 2016) - Produce all documents relating to the FDA's approval of Herceptin Labeling including its approval of any modifications to that labeling - **GRANTED. Requested discovery shall be produced from Defendant's described regulatory database and the custodial files of Dhushy Thambipilai, Ehab Taqiedden, and any other individuals who have had substantive involvement with FDA's approval of Herceptin labeling, including any modifications thereto.**

**2. Analysis**

The Court adopts its reasoning in Part III.A.2 and III.A.3.

**C. Documents Regarding Herceptin Labeling (III on JDS)**

**1. Rulings**

Request No. 3 (Oct. 2015): Produce all documents and communications concerning the Herceptin label and Prescribing Information for the years 1997 through the present - **GRANTED in part. Requested discovery shall be produced from Defendant's described regulatory database, custodial files, complaints database, information request database, and Herceptin**

**Touchpoint site. However, documents that exclusively address warnings/safety concerns that are unrelated to the amount or concentration of the Herceptin vials need not be produced.**

Request No. 10 (June 2016): Produce all documents relating to the removal of the reference to a “yield[]” of “21 mL of a multi-dose solution” from the Herceptin Prescribing Information, including but not limited to all correspondence with FDA on that topic. - **GRANTED. Requested discovery shall be produced from Defendant’s described regulatory database and custodial files.**

## **2. Analysis**

With respect to these requests, the Court adopts its reasoning in Part III.A.2 and III.A.3. In addition to that reasoning, the Court finds that Plaintiffs must be able to test Defendant’s expert’s assertion that Defendant could not consistently fill the vials with more than 440 mg of Trastuzamab without making changes that would require FDA approval.

## **D. Documents Concerning Mass, Volume, or Concentration (IV on JDS)**

### **1. Rulings**

Request No. 5 (Oct. 2015) - Produce all documents and communications between Genentech and any person concerning the mass, volume, or density of the medicine available in a Herceptin vial. - **GRANTED. Requested discovery shall be produced from Defendant’s described regulatory database, custodial files, complaints database, and information request database. This includes but is not limited to production from the custodial files of Dana Swisher, Toshiro Carcelen, Hung-Wei Chich, Raquel Iverson, Xanthe Lam, Karina Padilla, and Camellia Zamiri.**

Request No. 6 (Oct. 2015) - Produce all studies related to the mass, volume, or density of the medicine in a Herceptin vial. - **GRANTED. Requested discovery shall be produced from Defendant's described regulatory database and custodial files. This includes but is not limited to production from the custodial files of Dana Swisher, Toshiro Carcelen, Hung-Wei Chich, Raquel Iverson, Xanthe Lam, Karina Padilla, and Camellia Zamiri.**

Request No. 7 (Oct. 2015) - Produce all documents concerning the density of multi-dose Herceptin if the medicine is reconstituted following the directions in the Prescribing Information. - **GRANTED. Requested discovery shall be produced from Defendant's described regulatory database and custodial files. This includes production from the custodial files of Dana Swisher, Toshiro Carcelen, Hung-Wei Chich, Raquel Iverson, Xanthe Lam, Karina Padilla, and Camellia Zamiri.**

Request No. 13 (June 2016): Produce the results of all testing and measurements done to determine the concentration of the reconstituted solution in each vial of the drug. - **GRANTED. Requested discovery shall be produced from Defendant's described regulatory database and custodial files. This includes but is not limited to production from the custodial files of Dana Swisher, Toshiro Carcelen, Hung-Wei Chich, Raquel Iverson, Xanthe Lam, Karina Padilla, and Camellia Zamiri.**

## 2. Analysis

With respect to these requests, the Court adopts its reasoning in Part III.A.2 and III.A.3. The Court rejects Defendant's argument that, even if additional documents exist, they would be cumulative and would not "meaningfully alter the preemption analysis." (JDS 38.) Defendant produced documents and relies upon documents that provide Plaintiffs a preview of what else may

exist in its internal files but then asks the Court to limit Plaintiffs' discovery to its current production. The Court recognizes and commends Defendant's substantial discovery efforts thus far; however, the Court is not persuaded that Plaintiffs are engaged in an overly burdensome fishing expedition. If one document certainly exists saying "x," – which is relevant to overcoming a preemption defense – it is not overly speculative that other similar documents exist in Defendant's files.

#### **E. Documents Regarding Patheon's Herceptin Production (V on JDS)**

##### **1. Rulings**

Request No. 1 - Produce all documents, agreements or communications involving Genentech and Patheon, Inc. (formerly known as Dutch State Mines Pharmaceuticals, Inc.) that contain or reference manufacturing or production standards or processes for Herceptin. - **GRANTED.** **Requested discovery shall be produced from Defendant's described regulatory database and custodial files. Defendant shall produce any relevant Supply Agreements and Quality Agreements between Defendant and Patheon.**

Request No. 2 - Produce all records that identify or reference any lot manufactured by Patheon, Inc. (formerly known as Dutch State Mines Pharmaceuticals, Inc.), but not accepted unconditionally by Genentech. - **GRANTED. Responsive discovery contained in the Annual Product Quality Reviews shall be produced.**

Request No. 3 - Produce all quality control, process control, or other audits that refer or relate to the work done by Patheon, Inc. (formerly known as Dutch State Mines Pharmaceuticals, Inc.) for Genentech. - **GRANTED. Responsive discovery contained in the Annual Product Quality Reviews, Certificates of Analysis Quality Agreements, or reports of periodic audits shall be**

**produced.**

## **2. Analysis**

The Court adopts its reasoning in Part III.A.2 and III.A.3. In addition, the Court finds that Plaintiffs are entitled to explore (1) the accuracy of Swisher’s declaration that raising the lower fill limit would simultaneously raise the upper fill limit; and (2) whether noticeable shifts occurred in the amount of Herceptin in each vial during various time periods. Defendants argue that the number of rejected lots is irrelevant because these batches never reached customers. However, Phase I – necessitated by Defendant’s preemption defense – is not devoted to the substantive claims. In Phase I, Plaintiffs are entitled to discovery relevant to defeating the preemption argument, which includes (even under the narrowest legal inquiry) whether Defendant acquired new information that would have permitted a unilateral label change.

## **F. Drafts of the Chemistry, Manufacturing, and Controls Section of the BLA (VI on JDS)**

### **1. Rulings**

Request No. 4 (June 2016) - Produce all draft versions of the “Chemistry, Manufacturing and Controls” section of the Herceptin Biologics License Application submitted to the FDA by Genentech. - **GRANTED. Requested discovery shall be produced from Defendant’s described regulatory database and custodial files.**

Request No. 5 (June 2016) - Produce all supplements or amendments, including draft versions, to the “Chemistry, Manufacturing and Controls” section of the Herceptin Biologics License Application submitted to the FDA by Genentech. **GRANTED. Requested discovery shall be produced from Defendant’s described regulatory database and custodial files.**

## **2. Analysis**

The Court grants these requests based upon its reasoning in Part III.A.2 and/or Part III.A.3 and for consistency with its rulings in Part III.B.

However, as explained in Part III.A.3, the Court rejects Plaintiffs' argument that "if draft versions of the BLA or its supplements or amendments indicate [Defendant] knew those numbers were inaccurate or misleading, this would show [Defendant] could have used the correct number in the BLA and its original labeling." (JDS 48.) This is an impermissible "fraud on the FDA" argument. The Court also rejects Plaintiffs' reliance on *Trahan v. Sandoz, Inc.*, No. 3:13-CV-350-J-34MCR, 2015 WL 2365502 (M.D. Fla. Mar. 26, 2015). In *Trahan*, the court denied a generic drug manufacturer's motion to dismiss based on impossibility preemption, reasoning that, although regulations prevented the defendant from altering its glass container after FDA approval, no relevant regulations prevented the defendant from choosing a safer glass vial prior to FDA approval. *Id.* at \*6. The plaintiff alleged the defendant "breached its duty to design a reasonably safe product when it initially selected the defective glass, prior to FDA approval." *Id.* The court had concluded that, in contrast to quality/quantity requirements for generic drugs, the FDA did not appear to require identical packaging for generic drugs – meaning federal law did not make it impossible to comply with state-law design safety standards. Here, Defendant is a brand-name manufacturer who submitted a new drug application, and any allegedly "inaccurate or misleading" information was part and parcel of the approval process. Therefore, the Court grants these requests but not for the purpose of showing that Defendant somehow misled FDA during the approval process.

## G. Interrogatories Seeking Identity of Individuals (VII on JDS)

### 1. Rulings

Interrogatory No. 2 (Oct. 2015) - Identify each person who was employed by, affiliated with, or acting in an agent capacity for Genentech and has knowledge regarding the following matters:

...

(c) The Herceptin label and Prescribing Information - **GRANTED in part.** Defendant shall identify all current employees and the two former employees who are most likely to have relevant information.

(d) The FDA approval of Herceptin, its label, and its Prescribing Information - **GRANTED in part.** Defendant shall make efforts to identify all current employees and the two former employees who are most likely to have relevant information.

Interrogatory No. 10 (October 2015) - Identify all persons who helped prepare each change to the Herceptin label and Prescribing Information identified in response to Interrogatory No. 9. - **GRANTED in part.** Defendant shall make efforts to identify all current employees and the two former employees who are most likely to have relevant information.

Interrogatory No. 11 (June 2016) - Identify all persons and/or entities who have determined the concentration of the reconstituted Herceptin solution in any vial of the drug. - **GRANTED in part.** Defendant shall make efforts to identify all current employees and the two former employees who are most likely to have relevant information.

### 2. Analysis

These interrogatories are relevant for the same reasons articulated in Part III.A.2 and III.A.3. The Court limits the number of former employees to two in order to avoid an overly burdensome

inquiry for Defendant. Defendant should focus its efforts on identifying individuals who are most likely to have relevant information.

#### **IV. Defendant's Motion for Protective Order (Doc. 124)**

Plaintiffs issued subpoenas to the following third parties: Patheon Pharmaceutical Services, Inc. and Patheon Manufacturing Services LLC (collectively, "Patheon"); Cardinal Health; McKesson Specialty Health CuraScript, Inc.; US Oncology Pharmaceutical Services, LLC; Oncology Therapeutics Network Corporation; Besse Medical; Integrated Commercialization Solutions, Inc. dba BioSolutions Direct; ASD Specialty Healthcare, Inc.; and AmerisourceBergen Specialty Group, Inc. (collectively, "Distributors").

##### **A. Patheon**

###### **1. Rulings**

- 1) All documents, agreements or communications involving Patheon Pharmaceutical Services and Genentech that contain or reference manufacturing or production specifications, standards, or processes for multi-dose vials of Herceptin. - **DENIED**.
- 2) All records that identify or reference any lot of Herceptin manufactured by Patheon Pharmaceutical Services that was not accepted unconditionally by Genentech. - **DENIED**.
- 3) All quality control, process control, or other audits that refer or relate to the work done by Patheon Pharmaceutical Services for Genentech. - **DENIED in part. The Court compels production of all quality control, process control, or other audits that refer or relate to the work done by Patheon Pharmaceutical Services for Genentech *in relation to Herceptin*.**
- 4) All communications from Genentech, or a person or entity acting on its behalf, to Patheon Pharmaceutical Services about either (i) target fill weight for the harvested drug substance to be used

in multi-dose vials of Herceptin, or (ii) target vial fill for multi-dose vials of Herceptin. - **DENIED**.

## 2. Analysis

With respect to the subpoena issued to Patheon, a contract manufacturer of Herceptin, Defendant argues that it has produced all documents possibly relevant to preemption and that Patheon “cannot make changes to the Herceptin manufacturing, specification, or labeling - unilateral or otherwise.” (Mot. for Protective Order 9.) Plaintiffs make the same relevance arguments discussed above in Part III.A.2 regarding impossibility preemption and contend Patheon’s documents are relevant to, *inter alia*: (1) testing Swisher’s assertions regarding the manufacturing process and the effect of modifications thereof on the FDA-approved protein content specification; and (2) determining the cause of shifts in average fill weights.

For the same reasons explained in Part III.A.2 and Part III.E.2, the Court finds these documents relevant to impossibility preemption. With the addition of language limiting production to documents relating to Herceptin, the Court finds the requests not overly broad or burdensome.

## B. Distributors

### 1. Rulings

1) All communications, complaints or inquiries, received by You from a practice group, or made by

You to Genentech about the mass, concentration, or reconstituted volume of multi-dose vials of

Herceptin. - **DENIED**.

2) All communications, responses, and documents received from Genentech about any complaint

or inquiry concerning the mass, concentration, or reconstituted volume of multi-dose vials of

Herceptin. - **DENIED**.

3) All communications, complaints or inquiries made to the FDA about the mass, concentration, or

reconstituted volume of multi-dose vials of Herceptin. - **DENIED.**

- 4) All communications, responses, and documents received from the FDA about any complaint or inquiry concerning the mass, concentration, or reconstituted volume of multi-dose vials of Herceptin.  
- **DENIED.**

## 2. Analysis

These requests are relevant for the reasons articulated in Part III.A.2.

## V. Conclusion

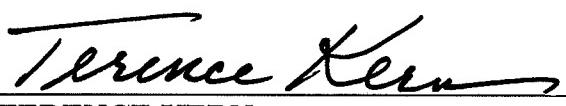
Plaintiffs' Motion to Compel (Doc. 64) is GRANTED in part and DENIED in part as set forth herein. Defendant's Motion for Protective Order (Doc. 124) is DENIED.<sup>2</sup> The parties are Ordered, as soon as practicable, to meet and confer to discuss ESI protocols, including any necessary negotiation of agreed-upon search terms or other negotiations necessitated by this Order.

This Court will rule on Plaintiffs' First Application to Remove Confidential Designation from Genentech Produced Documents (Doc. 179) by written Order.

If there are other outstanding discovery issues, the parties shall file a Second Joint Discovery Submission outlining the remaining issues no later than three weeks from the date of this Order.

Plaintiff's Motion for Discovery Conference (Doc. 205) is DENIED as moot.

**SO ORDERED this 8<sup>th</sup> day of May, 2017.**



TERENCE KERN  
United States District Judge

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<sup>2</sup> This Opinion and Order rules upon and terminates the identical motions to compel and motions for protective order filed in the underlying consolidated cases.